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Australian Government

National Animal Health Diagnostics Business Plan 2021 to 2026: project updates November 2024

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Cataloguing data

This publication (and any material sourced from it) should be attributed as: Australian Government 2024, *National Animal Health Diagnostics Business Plan 2021 to 2026: project updates November 2024*, Department of Agriculture, Fisheries and Forestry, Canberra, November. CC BY 4.0.

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Acknowledgements

The authors thank stakeholders for their input into this project update report.

Acknowledgement of Country

We acknowledge the continuous connection of First Nations Traditional Owners and Custodians to the lands, seas and waters of Australia. We recognise their care for and cultivation of Country. We pay respect to Elders past and present, and recognise their knowledge and contribution to the productivity, innovation and sustainability of Australia's agriculture, fisheries and forestry industries.

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Introduction

The National Animal Health Diagnostics Business Plan 2021 to 2026 (NAHDBP) aims to further develop and strengthen the animal health diagnostics component of Australia's animal health system. Animal health professionals and diagnostic experts from governments, private laboratories and the university sector collaborated to develop the NAHDBP.

The NAHDBP guides the efficient and effective delivery of nationally coordinated activities to maintain and continually improve our national diagnostic capability and capacity. It is consistent with nationally agreed principles and objectives for biosecurity as defined under <u>Australia's Intergovernmental Agreement on Biosecurity</u> and, importantly, it complements the <u>Animalplan 2022</u> to 2027.

Responsibility for implementing elements within the NAHDBP resides with the Subcommittee on Animal Health Laboratory Standards (SCAHLS), with guidance and oversight from the Animal Health Committee (AHC), support from livestock industries through Animal Health Australia and funding identified through various sources.

This report provides an overview on the progress of each project linked to a NAHDBP objective. It summarises the project activities supported by the department. However, it does not cover all activities conducted under the NAHDBP from 2021 to 2026. Future reports may include activities across additional stakeholder groups.

For further information on the listed projects, email <u>animalhealthlaboratories@aff.gov.au</u>.

To enable high-throughput sequencing (HTS) usage and the application of HTS data to enhance animal disease investigations.

Table 1 Objective 1 projects

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Australian Biosecurity Genomic Database (ABGD) for notifiable terrestrial animal viruses: Phase 1	 AgriBio (Victoria) Department of Agriculture, Fisheries and Forestry (DAFF) 	This project developed a verified genomic database of notifiable terrestrial animal disease viruses in Australia to facilitate a more robust and efficient application of HTS for Australian biosecurity surveillance and disease detection.	Complete	Nil	Nil
ABGD for notifiable animal pathogens: Phase 2	AgriBio (Victoria)DAFF	This project built upon ABGD Phase 1 by expanding the database to include verified sequences from viruses associated with Australia's national list of reportable diseases of aquatic animals. In addition, 10 new verified whole genome sequences from recent local terrestrial and aquatic outbreaks were uploaded improving utility of the database.	Complete	Nil	Nil
Developing lumpy skin disease (LSD) and African horse sickness whole genome sequencing workflows	 CSIRO Australian Centre for Disease Preparedness (ACDP) DAFF 	This project developed robust whole genome sequencing procedures for both LSD virus and African horse sickness virus to mitigate the consequences of their outbreaks in Australia. The genomic sequencing probes and procedures, now available at ACDP, will be an invaluable resource in the event of an LSD outbreak in Australia.	Complete	Nil	Nil

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Northern Australia biosecurity sequencing (NABSeq): HTS network and facility to enhance northern Australian biosecurity	 Berrimah Veterinary Laboratory (Northern Territory) CSIRO ACDP DAFF 	This project aims to improve northern Australia's ability to identify and respond to future biosecurity challenges; and provide more effective biosecurity risk management through modernisation of disease detection resources and surveillance in the region.	Delayed	NABseq continues to enhance northern Australia's ability to respond to biosecurity challenges and develop a collaborative HTS facility and network, based at the Berrimah Farm Science Precinct. Outbreak responses have delayed this project.	The next milestone report will be rescheduled to accommodate delays experienced, and it is anticipated the project will be completed by September 2025.
Quality assurance for HTS as an infectious agent discovery tool	CSIRO ACDPDAFF	DP This project aims to establish standardised workflows for the use of HTS in infectious agent discovery. It will support relevant national diagnostic HTS operating guidelines and improve overall quality assurance, allowing for high confidence when interpreting HTS results.		Outbreak responses have delayed this project.	The final milestone report will provide evidence of optimised HTS workflows and ACDP approved standard operating procedures. These will be submitted to SCAHLS for evaluation and national approval, and subsequent adoption by the Laboratories for Emergency Animal Disease Diagnosis and Response (LEADDR) network.
ABGD : Phase 3	 AgriBio (Victoria) DAFF 	This project builds on previous phases of the ABGD project. Phase 3 aims to add additional viral subtypes, expand to state based notifiable diseases, trial the inclusion of bacterial pathogens, and determine a long-term solution for database maintenance.	On track	Since commencement, more pathogens have been added to the database and a <u>manuscript</u> has been accepted into the journal Database: The Journal of Biological Databases and Curation.	The next milestone report is due in late November 2024. Project deliverables include an improved ABGD, an eLearning module, and a published webpage on an appropriate website that can be maintained long term.

To scope and improve the national surge capacity of laboratory networks, including both government and non-government laboratories, during emergency animal disease (EAD) responses.

Table 2 Objective 2 projects

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Sample Tracking and Reporting System (STARS) enhancement	CSIRO ACDPDAFF	This project redeveloped the CSIRO- STARS network for enhanced biosecurity and laboratory management system interoperability at both national and jurisdictional levels. The expansion of software capability and improved performance to facilitate integration of a wider group of users to the network will improve Australia's ability to respond to EAD outbreaks.	Complete	Nil	Nil
National laboratory simulation exercise planning	 SCAHLS DAFF All jurisdictional animal health laboratories 	SCAHLS, through leadership of DAFF and an expert consultant, have completed the process of finalising a business plan to guide the roadmap for a national laboratory-focused simulation exercise. This exercise will assist in the identification of training and means by which to improve the surge capacity of Australian animal health laboratory networks in response to major EAD outbreaks.	Complete	Nil	Nil

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Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
National laboratory simulation exercise (Exercise Waterhole)	 SCAHLS DAFF All jurisdictional animal health laboratories 	Following a scoping report completed in 2022, Exercise Waterhole included a series of discussion workshops over September and October 2023 and concluded with a functional exercise in early November 2023. The exercise activities tested and evaluated national laboratory preparedness for a major emergency animal disease incursion across the spectrum of laboratory services in Australia. A dual disease scenario was simulated involving a primary outbreak of LSD in northern Australia, and a concurrent outbreak of highly pathogenic avian influenza (HPAI) in southern Australia.	Complete	Nil	Nil
Building a sustainable national sample identification system for animal diagnostics - A pilot study using pre-barcoded sample collection tubes	 AgriBio (Victoria) CSIRO ACDP Gribbles Veterinary Laboratory – Department of Primary Industries and Regions (South Australia) DAFF 	This project will investigate pre- barcoded sample tubes to mitigate the bottleneck of manual labelling in disease outbreak responses. It includes researching technologies and suppliers of pre-barcoded sample collection tubes. AgriBio conducted several pilot trials of selected sample tubes from the field to the laboratory. A trial will also be conducted with the South Australian animal health laboratory service and ACDP to test its potential for use as a national system.	Delayed	Since commencement, potential suppliers have been selected and initial trials have commenced.	The next milestone report was rescheduled for completion in late November 2024 and will include findings from the initial small trials and agreement on large-scale trial design.

Introduce a suite of validated diagnostic assays to LEADDR laboratories targeting priority disease threats to Australian animal species.

Table 3 Objective 3 projects

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Evaluation of antibody- detecting immunoassays for LSD in cattle and buffalo	CSIRO ACDPDAFF	This project will evaluate the suitability of 3 antibody detection enzyme-linked immunosorbent assays (ELISAs) for LSD surveillance, and proof-of- freedom testing, in cattle and buffalo in Australia. The ELISA kits will be made available for use by Australian laboratories via the LEADDR network.	Delayed	This project continues to evaluate the suitability of 3 ELISAs for LSD testing in cattle and buffalo in Australia. Reference positive and negative serum samples, sourced overseas and in Australia, will be further analysed this year using an upscaled commercial partner-supplied indirect ELISA, alongside existing ELISA capabilities. The ELISA kits will be made available for use by Australian laboratories via the LEADDR network. The launch is anticipated for late 2024.	Additional samples from northern Australian and southeast Asia will be tested at ACDP or in country-of-origin. The project is due for completion by February 2025.
Establishing networked serological testing capability for African Swine Fever	 The LEADDR network CSIRO ACDP DAFF 	This project established an improved serological testing capability for African swine fever in Australia by harmonising quality assurance processes and antibody-detection ELISA capability via the LEADDR network.	Complete	Nil	Nil

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
LSD testing capacity building in the LEADDR network	 The LEADDR network CSIRO ACDP DAFF 	This project will reinforce and extend Australia's LSD testing capability by strengthening the capability of ACDP to participate in international proficiency testing (PT) and facilitating a robust and quality- assured national capability through implementation of PT and monitoring for the disease via the LEADDR Network.	Delayed	This project continues to progress the roll-out of molecular, real-time quantitative polymerase chain reaction (qPCR) and serological, ELISA capabilities to the LEADDR network as planned.	The next milestone report will be rescheduled to accommodate delays, and it is anticipated the project will be completed by June 2025. This report will outline the outcomes of the first LEADDR PT round for qPCR and ELISA, and progress on the second round. This project is due for completion in March 2025.
MicroRNA biomarkers for improved detection of animal diseases in a Johne's disease (JD) model	CSIRO ACDPDAFF	This project will evaluate the use of host microRNA for detection of JD in cattle and will provide a proof of concept for the potential extension of this approach to other EADs.	Delayed	The project has completed further sequencing for host microRNA in an expanded collection of JD reference material. Cattle microRNA biomarkers of JD continue to be characterised and selected for molecular assay development and assessment of diagnostic performance. A stakeholder workshop on JD diagnostics was held at ACDP in September 2024.	Further sequencing of selected reference material continues. A PCR based biomarker assay in calves and heifers will be assessed for analytical and diagnostic performance. This project is due for completion in January 2025.
Developing immunohistochemistry (IHC) test for LSD	CSIRO ACDPDAFF	This Australian Centre for Disease Preparedness (ACDP) project developed and characterised an IHC test for the diagnosis and investigation of LSD virus.	Complete	Nil	Nil
Equine piroplasmosis (EP) diagnostic capability development	CSIRO ACDPDAFF	This project aims to enhance ACDPs serological diagnostic capabilities for EP, caused by <i>Theileria equi</i> and <i>Babesia caballi</i> .	Delayed	Testing and analysis of the <i>T. equi</i> competitive ELISA and immunofluorescence antibody test (IFAT), and the <i>B. caballi</i> cELISA is now complete. Optimisation of <i>B. caballi</i> IFAT is ongoing.	Milestone 4 is due in November 2024. The final report will cover the development and verification of the EP ELISA and IFAT, and the submission of accreditation documents to National Association of Testing Authorities (NATA).

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Improve national diagnostic capability for glanders	CSIRO ACDPDAFF	This project aims to enhance our national diagnostic capabilities for glanders, caused by the bacterium <i>Burkholderia</i> <i>mallei</i> .	On track	Assessment and verification of current commercial tests and developing a fit- for-purpose testing algorithm for the laboratory diagnosis of glanders has commenced. The project team will also seek to gain NATA accreditation for the new diagnostic method.	The next milestone report outlining verified procedures for ELISAs and PCR tests for glanders is due April 2025. The final project report providing evidence of documents submitted for NATA accreditation and is due June 2025.
Assessment and improvement of national bluetongue serological capability - a comparative study of commercial and in- house ELISAs	CSIRO ACDPDAFF	This project aims to measure, assess, and improve on current bluetongue virus (BTV) serological capabilities in Australia to support national BTV surveillance and response activities.	On track	BTV <i>in-house</i> ELISAs are in final stages of development, and commercial ELISA kits have been procured. A <u>manuscript</u> outlining the complexities of BTV-group specific serology testing has been published the peer-reviewed journal <i>Viruses</i> .	The final milestone, due in June 2025 will include a final report detailing the evaluation of a fit-for-purpose diagnostic algorithm. The final milestone also includes evidence of documents submitted for NATA accreditation and, where applicable, a peer-reviewed journal manuscript for publication.
Improvement of serological testing for flaviviruses in Australian livestock	 CSIRO ACDP DAFF 	This project aims to develop a bead-based multiplexed serological (Luminex) assay for the differential diagnosis of various flaviviruses, suitable for use in pigs and horses. Successful uptake of this new serological approach at ACDP will enable faster, higher-throughput testing, and more sensitive/specific testing for flaviviruses in relevant livestock species.	On track	The procurement of reagents, reference sera, and known positive controls; and standardisation of the gold-standard plaque reduction neutralisation test is complete. Recombinant protein manufacture at CSIRO is ongoing.	The final milestone due in June 2025. It will include the final project report on all activities described within the proposal, and a draft validation dossier document suitable for submission to SCAHLS for test evaluation.

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Towards validation of a microRNA-based diagnostic test for JD	CSIRO ACDPDAFF	This project will further develop molecular assays using host microRNA biomarkers to improve detection of JD.	On track	Networks for JD field sampling and testing have been established in Australia and New Zealand. Assessment of microRNA biomarker analytical specificity and diagnostic sensitivity, and assessment of overseas/historic sample integrity is in progress. A stakeholder workshop on JD diagnostics was held at ACDP in September 2024.	Milestone 2 report is due in April 2025. This will detail completion of the assessment of microRNA biomarker analytical specificity, and diagnostic sensitivity and specificity using a collection of relevant reference material from laboratory and field studies. It will also include completion of WOAH diagnostic validation stage 1-3 activities.
Assessment of molecular DIVA capabilities for LSD virus	CSIRO ACDPDAFF	This project commenced aims to assess existing molecular 'Differentiating Infected from Vaccinated Animals' (DIVA) assays that are based on real-time, or quantitative PCR, to determine if they are fit- for-purpose.	On track	Bioinformatic analysis is complete, and assay evaluation has commenced. A preferred LSD DIVA assay has been selected for further optimisation.	The final milestone report due January 2025 will contain an evaluation and recommendation on DIVA assays to be used for diagnostics and roll out to the LEADDR network.

Pilot the validation template process for point of care (POC) tests used for specific purposes.

Table 4 Objective 4 projects

Project title	Lead and key collaborators	Description	Status	Progress update	Next steps
Development and evaluation of a POC test network for EAD diagnosis	EMAI (NSW)DAFF	This project will develop a suite of tests on a portable, battery-operated multiplexing qPCR platform for the detection of major emergency diseases of cattle and pigs. It aims to establish a proof-of- concept for multiplexing qPCR assays for emergency animal pathogens suitable for use under field conditions.	Delayed	Outbreak responses have delayed this project.	The final laboratory and field validation trials of the POC platform is expected to be completed by December 2024. A finalised dossier describing the validation of porcine and bovine EAD field tests will be circulated to SCAHLS.
Consultancy for policies, strategies and operating guidelines for POC testing for infectious disease	• DAFF	This project supports development of a nationally consistent management approach towards the use of POC tests specific for national notifiable and reportable diseases in terrestrial and aquatic animals in Australia.	Complete	Nil	Nil

Establish processes to develop and harmonise antimicrobial susceptibility-related diagnostic procedures across all relevant animal health laboratories

No DAFF supported projects address this objective.

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Glossary

Term	Definition
ABGD	Australian Biosecurity Genomic Database
ACDP	Australian Centre for Disease Preparedness
AHC	Animal Health Committee
BTV	blue tongue virus
DAFF	Department of Agriculture, Fisheries and Forestry
DIVA	differentiating infected from vaccinated animals
EAD	emergency animal disease
ELISA	enzyme linked immunosorbent assay
EP	equine piroplasmosis
HPAI	high pathogenicity avian influenza
HTS	high-throughput sequencing
IFAT	immunofluorescence antibody test
IHC	immunohistochemistry
JD	Johne's disease
LEADDR	Laboratories for EAD Diagnosis and Response
LSD	lumpy skin disease
NABseq	Northern Australia biosecurity sequencing
NAHDBP	National Animal Health Diagnostics Business Plan
NATA	National Association of Testing Authorities
PCR	polymerase chain reaction
POC	point of care
PT	proficiency testing
qPCR	quantitative polymerase chain reaction
SCAHLS	Subcommittee on Animal Health Laboratory Standards